

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

ETHEL KELLOGG, :
 :
 Plaintiff, :
 :
 v. : Case No. 2:07-cv-82
 :
 WYETH, Individually and as Successor-in- :
 Interest to A.H. ROBINS COMPANY, INC. :
 and AMERICAN HOME PRODUCTS CORPORATION; :
 SCHWARZ PHARMA, INC.; ACTAVIS, INC.; :
 ACTAVIS-ELIZABETH, L.L.C.; ALPHARMA, :
 INC.; PUREPAC PHARMACEUTICAL COMPANY, :
 INC.; TEVA PHARMACEUTICALS, USA, INC.; :
 BAR PHARMACEUTICALS, INC.; PLIVA, INC.; :
 and DRUG COMPANY DOES 1 THROUGH 10, :
 inclusive, :
 :
 Defendants. :

OPINION AND ORDER

Plaintiff Ethel Kellogg brings suit against the brand name and generic manufacturers of metoclopramide ("MCP") for strict product liability, breach of express and implied warranties, negligent misrepresentation, fraud and fraud by concealment. She alleges that the medication caused her to develop tardive dyskinesia, a neurological disorder causing involuntary repetitive tic-like movements. Defendants Wyeth and Actavis, Inc. have moved for summary judgment. For the reasons that follow, the motions, ECF Nos. 204 & 211, are **denied**.

Factual Background

The following facts are either undisputed or presented in the light most favorable to Kellogg, as the non-moving party.

MCP is a prescription drug approved by the Federal Drug Administration ("FDA") for the treatment of symptoms associated with gastroesophageal reflux when a patient fails to respond to conventional therapy. MCP has been available for prescription use under the name brand Reglan® since the late 1970's.

Reglan® was originally developed and marketed by A.H. Robins Company ("AHR"). An oral tablet form of Reglan® was approved in 1980 for the treatment of hospitalized patients with acute diabetic gastroparesis. See Nelson Decl. ¶ 25, ECF No. 223-11. In 1984, Reglan® was approved for treatment of gastroesophageal reflux in the general population. See *id.* ¶ 26.

In 1985, AHR filed for bankruptcy. In 1989, AHR merged into AHP Subsidiary (9) Corporation, and ceased to exist. AHP Subsidiary (9) Corporation, a wholly-owned subsidiary of American Home Products Corporation, was renamed A.H. Robins Company, Inc., and carried on the surviving aspects of AHR's business. In 1998, A.H. Robins Company, Inc. merged into American Home Products Corporation, and became an unincorporated division of that company. On March 11, 2002, American Home Products Corporation changed its name to Wyeth.

In acquiring AHR, Wyeth acquired the rights to Reglan®, and manufactured and distributed it from 1989 through 2001. In December 2001, Wyeth transferred the rights to Reglan® tablets to

Schwarz Pharma, Inc.,¹ and ceased to manufacture and distribute Reglan®.

Since the mid-1980's, Reglan® tablets have also been available in generic form. Several companies, including Wyeth and its co-defendant Actavis, have manufactured and sold generic MCP tablets. Wyeth has not manufactured or distributed generic MCP tablets since December 27, 2001.

At the times relevant to this lawsuit, prescriptions of Reglan® and generic MCP tablets were accompanied by an FDA-approved label and package insert that contained instructions concerning the drug's use and warnings about risks associated with its use. According to this information, MCP was "indicated as short-term (4 to 12 weeks) therapy for adults with symptomatic, documented esophageal reflux who fail to respond to conventional therapy." Physicians' Desk Reference ("PDR") 2604 (54th ed. 2000), ECF No. 205-1. The information also included warnings that

extrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages These usually are seen during the first 24-48 hours of treatment with metoclopramide, occur more frequently in pediatric patients and young adults, and are even more frequent at the higher doses used in prophylaxis of vomiting due to cancer chemotherapy.

Id. The package insert also warned that tardive dyskinesia is a

¹ Schwarz Pharma, Inc. was dismissed from this suit on March 24, 2008.

possible side effect of MCP, and that "[b]oth the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose." *Id.* With respect to using the drug for relief of symptoms of gastroesophageal reflux, the package insert advised that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." *Id.* at 2605. Until 2002, when Wyeth ceased marketing Reglan®, this information for Reglan® was also published in the PDR, an annual compilation of manufacturers' prescribing information distributed to doctors. *See, e.g., id.* 2603-2605.

According to Kellogg's expert, Dr. Robert C. Nelson, from the mid-1970's through the mid-1980's, AHR pursued an aggressive marketing strategy for Reglan®, and underplayed or concealed the risks involved in the use of the drug for prolonged treatment of chronic gastrointestinal ailments. For example, AHR encouraged the use of Reglan® for "vague gastrointestinal complaints." Nelson Decl. ¶ 15, ECF No. 223-11. It promoted Reglan® as safe for long-term use, although it was aware that there were concerns that Reglan® tablets should not be used for longer than four to six weeks. *Id.* ¶ 12. It acknowledged that gaining approval for treatment of heartburn "would place the drug on the market for acute and chronic indefinite intermittent usage. Actual clinical usage should easily exceed the initially approved labeled

indications." *Id.* ¶ 11. It advised its sales force, when marketing the drug to doctors, to refer to a study showing that Reglan® was safe for long-term use, but cautioned its sales people not to allow access to the study data. *Id.* ¶ 17. In sum, Nelson's review of the Wyeth and AHR files on Reglan® shows a company bent on increasing the market for its drug by encouraging off-label use and fostering the impression among the medical community that the drug was relatively safe to administer for longer than the recommended duration of therapy.

Kellogg has a history of gastrointestinal disorders, which have been treated with a variety of prescription and non-prescription medications. In May 2000, Kellogg's physician, Dr. Meghan B. Cook, prescribed MCP tablets for her gastrointestinal condition. Dr. Cook testified that she prescribed MCP rarely, but had experience with it before she prescribed it for Kellogg. She was aware of some of the benefits and some of the side effects. Her sources of information included generally journal articles, lectures, the PDR and perhaps colleagues. Dr. Cook thought that extrapyramidal symptoms--in particular acute dystonic reactions--were rare, and she relied on the manufacturers to supply accurate information and to inform her if the information available to doctors about the drug was no longer accurate. Dr. Cook had referred to the Reglan® entry in the PDR in the past, but did not recall reviewing it before prescribing

MCP for Kellogg, and did not regard it as the chief source of her information about MCP. She did not recall whether she knew about or thought about the recommended four to twelve-week duration of therapy. She did not recall whether she discussed the potential side effects of MCP with Kellogg. Cook Dep. 56:12-64:10, 91:21-94:25, 100:5-11, Apr. 14, 2010, ECF No. 223-8.

Dr. Bradford Armstrong, Kellogg's physician from October 2001 through 2009, did not recall reviewing or relying on any label, package insert or PDR reference for MCP during or before the time he prescribed MCP for her. Nor did he recall receiving any information from sales representatives or conferences. He believed that he may have consulted a medical text, or learned about the drug in pharmacology class, or gotten his information from instructors during his medical training. He believed he was familiar with the risks of the drug. He believed that extrapyramidal effects were relatively rare, and that tardive dyskinesia was a very uncommon side effect. He did not recall whether he knew about the recommended four to twelve-week duration of therapy. He did expect, however, that new information would be brought to his attention, especially information indicating that the risk of a side effect was substantially greater than had been reported. Dr. Armstrong testified that had he been aware of the information that now accompanies MCP, he would have taken Kellogg off the medication.

Armstrong Dep. 11/18/2009, 22:16-19, 24:25-25:16, 60:23-61:1, 113:22-118:9, 122:3-123:15, 127:7-128:15, 131:5-24, 133:16-24, 135:19-136:15, 148:20-25, Nov. 18, 2009, ECF No. 223-7.

Kellogg took MCP from May 2000 through mid-June 2004. She did not read or rely upon the drug labeling or package insert for her information about the drug, but relied on her physicians to inform her. Her MCP prescriptions were filled exclusively with generic MCP tablets.² She never received or ingested Reglan® tablets. Two of Kellogg's prescriptions, from May 8, 2000 and January 1, 2001, were filled with Wyeth's generic MCP tablets. In late January and late February 2001, the prescription was refilled with generic MCP manufactured by Defendant Teva Pharmaceuticals, Inc. Between January 2002 and May 2004, the prescription was refilled with generic MCP manufactured by Defendants Actavis or Pliva, Inc.

Kellogg was diagnosed with tardive dyskinesia in September 2004. She suffers from involuntary grimacing, lip twisting and chewing, tongue thrusting, difficulty swallowing, uncontrolled pronation of her feet, gait instability, and difficulty controlling her hands and arms.

The medical consensus today is that MCP is likely to cause

² Under Vermont law a pharmacist must fill a prescription for a particular drug with its generic equivalent, unless the prescribing physician specifies that no substitution for a particular brand may be made. Vt. Stat. Ann. tit. 18, §§ 4605(a); 4606 (2002 & Supp. 2009).

tardive dyskinesia and other extrapyramidal reactions with about the same frequency as any neuroleptic drug, given comparable periods of exposure at usual doses, meaning that these side effects occur at rates many times greater than 1 in 500, and are not rare.

In 2009, the FDA required all manufacturers of MCP to include a new "Black Box Warning" in their informational materials:

Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. The elderly, especially elderly women, are most likely to develop this condition. . . . There is no known treatment for tardive dyskinesia; however, in some patients symptoms may lessen or resolve after metoclopramide treatment is stopped. Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.

Nelson Decl. ¶ 19. In addition, the informational materials accompanying MCP must now also warn that "[a]lthough the risk of tardive dyskinesia (TD) with metoclopramide has not been extensively studied, one published study reported a TD prevalence of 20% among patients treated for at least 3 months. *Id.*

In her lawsuit, filed in 2007, Kellogg alleges that the risk of tardive dyskinesia among long-term MCP users was considerably higher than described on the label for the drug at the time she was taking it, and that all defendants knew this to be true. She

alleges that the labels and other information supplied for Reglan® and generic MCP failed to warn doctors and patients adequately about the risk of long-term use, and should have emphasized that long-term users were at higher risk for developing tardive dyskinesia than short-term users. Her eight-count complaint asserts causes of action for negligent misrepresentation and fraud against Wyeth as the brand name manufacturer, and products liability and breach of express and implied warranties against the generic manufacturers of MCP.

Wyeth seeks summary judgment on all the claims asserted against it, on the grounds that Kellogg lacks admissible evidence that her injuries were caused by Wyeth's failure to warn; that Kellogg's breach of warranty claims are time-barred; and that Wyeth as the brand name manufacturer is not responsible for any injuries caused by ingestion of the generic form of the drug.

Actavis also seeks summary judgment on all claims asserted against it (counts 4 through 8) on the ground that Kellogg lacks admissible evidence that her injuries were caused by its failure to warn.

Discussion

I. Summary Judgment Standard

Summary judgment should be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and

that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 12(c)(2); see, e.g., *Bronx Household of Faith v. Bd. of Educ. of the City of New York*, 492 F.3d 89, 96 (2d Cir. 2007). The burden rests on the moving party to show the absence of a genuine factual dispute. See, e.g., *Vermont Teddy Bear Co. v. 1-800 Beargram Co.*, 373 F.3d 241, 244 (2d Cir. 2004).

A material fact is one that would affect the outcome of the suit under the governing law, and a dispute about a genuine issue of material fact occurs if the evidence is such that a reasonable [factfinder] could return a verdict for the nonmoving party. In determining whether there is a genuine issue of material fact, a court must resolve all ambiguities, and draw all inferences, against the moving party.

Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of New Jersey, Inc., 448 F.3d 573, 579 (2d Cir. 2006) (quotations and citations omitted). The moving party will be "entitled to a judgment as a matter of law [if] the non-moving party 'fails to make a showing sufficient to establish the existence of an element essential to that party's case.'" *Tufariello v. Long Island R. Co.*, 458 F.3d 80, 85 (2d Cir. 2006) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

II. Failure to Warn

Under Vermont law,³ to withstand a motion for summary judgment on a failure to warn claim, Kellogg must show that she

³ The parties agree that the substantive law of the state of Vermont applies in this diversity case. See *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78-79 (1938).

has admissible evidence that 1) the drug manufacturer defendants had a duty to warn; 2) the lack of an adequate warning made the product unreasonably dangerous, and therefore defective; and 3) the lack of an adequate warning was a proximate cause of the injury. See *Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343, 347 (Vt. 1997); *Menard v. Newhall*, 373 A.2d 505, 506 (Vt. 1977); accord *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995) (applying Vermont law).

A. Duty to Warn

In jurisdictions that have adopted the learned intermediary doctrine, a prescription drug manufacturer's duty is to warn physicians about the risks associated with use of the drug, and not the consumers of the drug. See, e.g., *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164-65 (Ohio 2002). If the manufacturer adequately warns the prescribing physician, the manufacturer need not have communicated a warning directly to the patient who consumes the drug. See, e.g., *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 207 (5th Cir. 2008) (discussing the doctrine under Texas law); *Wright ex rel. Trust Co. of Kansas v. Abbott Labs., Inc.*, 259 F.3d 1226, 1233 (10th Cir. 2001) ("The 'learned intermediary doctrine' states that once a manufacturer warns a doctor about a drug's inherent dangers, it has fulfilled its legal duty to provide a warning," applying Kansas law). Some jurisdictions have rejected or recognized exceptions to the

learned intermediary doctrine. *See, e.g., State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 906, 914 (W. Va. 2007) (declining to adopt the learned intermediary exception, finding the justifications for the doctrine to be “largely outdated and unpersuasive”); *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1257-58 (N.J. 1999) (concluding that the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers).

Vermont has neither adopted nor rejected the learned intermediary doctrine. The parties, however, agree that the defendant drug manufacturers’ duty in this case is to have provided an adequate warning to her prescribing physicians, rather than to Kellogg herself. Pl.’s Mem. in Opp’n 4 & n.3, ECF No. 223; Def. Wyeth’s Mot. for Summ. J. 10, ECF No. 204; Def. Actavis’s Mot. for Summ. J. 4-5, ECF No. 211. Because the parties agree that the defendant drug manufacturers owed a duty to provide an adequate warning to Kellogg’s prescribing physicians, it is unnecessary for this Court to predict whether the Vermont Supreme Court would adopt the learned intermediary doctrine.

B. Inadequate Warning

Wyeth and Actavis appear to concede that whether the warnings they provided to physicians were adequate is an issue that must be presented to the jury, given that they have not sought summary judgment on this element. The question whether

Wyeth and Actavis provided accurate and adequate warnings is appropriately left to the jury. *See McCulloch*, 61 F.3d at 1045; *see also, e.g., McNeil v. Wyeth*, 462 F.3d 364, 368 & n.4 (5th Cir. 2006) (applying Texas law, which "generally holds that the adequacy of a product's warning is a question of fact to be determined by the jury," and observing that "[w]arning the learned intermediary of a much lower risk than the actual risk could render the warning not just misleading, but ineffective."); *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993) (holding that the trier of fact must determine the credibility and materiality of testimony that a treating physician would not have warned his patient had he known of the danger, applying New York law).

C. Proximate Cause

Under Vermont law, proximate cause in a failure to warn case "is typically shown by means of a presumption. If a plaintiff can demonstrate that the manufacturer had a duty to warn and failed to provide an adequate warning, a causal presumption arises that had an adequate warning been provided, the user would have read and heeded the warning. . . ." *Town of Bridport v. Sterling Clark Lurton Corp.*, 693 A.2d 701, 704 (Vt. 1997); *accord Needham v. Coordinated Apparel Group, Inc.*, 811 A.2d 124, 129 (Vt. 2002). Operation of the presumption shifts the burden of production to the manufacturer. *Menard*, 373 A.2d at 506. Thus,

if the manufacturer can show that the user was warned of the risk and chose to ignore the warning, the presumption disappears, because "there is no reasonable basis to assume that the user would have heeded a warning from the manufacturer." *Town of Bridport*, 693 A.2d at 704.

Wyeth and Actavis argue that the evidence at trial will show that Kellogg's doctors never read or relied upon their labeling, and that therefore her claims cannot survive summary judgment, citing *Town of Bridport*, *id.* at 705.⁴ They have selectively marshaled the facts in support of their argument, and have read the holding of *Town of Bridport* too broadly.

It is true that neither Dr. Cook nor Dr. Armstrong recalled consulting either the drug labeling or the PDR reference for MCP prior to prescribing the drug for Kellogg. Dr. Cook testified that she was familiar with the drug, and that her usual sources of information included the PDR. She had referred to the PDR entry for Reglan® in the past. She believed that extrapyramidal symptoms were rare. She did not recall the statement that treatment with MCP for longer than twelve weeks "cannot be recommended."

Dr. Armstrong testified that he believed he was aware of the

⁴ *Town of Bridport* involved the spontaneous combustion of floor-refinishing products. Vermont has not had occasion to apply the read and heed presumption in a prescription drug case; this Court assumes, as the parties do, that the presumption applies in this context.

risks, believed that extrapyramidal effects were relatively rare, and believed that tardive dyskinesia was a very uncommon side effect. He also did not recall the statement that use of the drug for longer than twelve weeks "cannot be recommended." Had he been aware of the warning that is now provided with the drug, he would have ceased prescribing it for Kellogg.

In *Town of Bridport*, a defendant chemical manufacturer argued that evidence that the product users did not read warnings on the product containers rebutted the "read and heed" presumption, leaving no evidence of proximate cause. *Id.* at 704. The Vermont Supreme Court rejected this argument, drawing a distinction between the user who is accurately warned and ignores the advice, and the user who is not aware of the risk: "if the user is cautioned of the risk and ignores that advice, there is no reasonable basis to assume that the user would have heeded a warning from the manufacturer. . . ." *Id.* In contrast, where a user was not aware of the risk, a "claim that inadequate warnings were a proximate cause of the accident does not fail as a matter of law merely because [the user] did not read the warnings." *Id.* Moreover, "manufacturers remain responsible for updating their labels" to strengthen warnings if additional risk information becomes available after a drug's initial approval. *Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009).

Kellogg has alleged that the warnings provided in the PDR

and the drug labeling and package inserts--and the dissemination of information concerning MCP's risks--were inadequate, inaccurate and misleading. She has presented evidence that her doctors were not accurately informed of the risk of developing tardive dyskinesia from chronic treatment with MCP. She has presented evidence that had Dr. Armstrong been accurately informed he would have taken her off the drug. Kellogg's claim does not fail as a matter of Vermont law merely because a jury could conclude that her doctors did not read the allegedly inadequate warnings provided. *See id.* A drug manufacturer is not shielded from liability if the warnings it provides to physicians would not enable the physicians to accurately and adequately advise their patients. A reasonable jury could conclude that inadequate, misleading and inaccurate information provided by the Defendants was a proximate cause of her injury; accordingly, Wyeth and Actavis are not entitled to summary judgment for lack of a triable issue on proximate cause.

III. Statute of Limitations

Counts 7 and 8 of Kellogg's Second Amended Complaint assert breach of warranty claims. If, as Wyeth argues, the relevant statute of limitations is one for breach of warranty in connection with a sales contract, these claims are time-barred. If, as Kellogg argues, the three-year personal injury statute of limitations applies, then her claims were timely filed.

Section 512(4) of Title 12 of Vermont Statutes Annotated provides that personal injury actions must be commenced within three years after the cause of action accrues. Vt. Stat. Ann. tit. 12, § 512(4) (2002). Kellogg's complaint was filed March 30, 2007, within three years of her diagnosis in September 2004.

Section 2-725 of Title 9A addresses the statute of limitations in contracts for sale, and provides in relevant part:

(1) An action for breach of any contract for sale must be commenced within four years after the cause of action has accrued. . . .

(2) A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made

Vt. Stat. Ann. tit. 9A, § 2-725(1), (2) (1994). Kellogg last obtained MCP produced by Wyeth in January, 2001; therefore, if these sections apply, she should have filed her complaint by January 2005.

It has been settled law in Vermont for nearly one hundred years that the applicability of section 512 depends "upon the nature of the harm for which recovery is sought and not upon the nature of the action brought." *Kinney v. Goodyear Tire & Rubber Co.*, 367 A.2d 677, 680 (Vt. 1976) (citing Public Act No. 88, § 2 (1915)); see also *Fitzgerald v. Congleton*, 583 A.2d 595, 598 (Vt. 1990) (discussing *Kinney*). In *Kinney*, the plaintiff brought claims of breach of express and implied warranties against a tire manufacturer and a tire seller in connection with personal

injuries sustained when a new tire burst. The Vermont Supreme Court looked to the nature of the harm suffered, rather than the label on the cause of action, and concluded that the personal injury statute of limitations applied. *Kinney*, 367 A.2d at 680.

Wyeth insists that Kellogg's claims arise out of a sale of goods, that Kellogg was in privity with Wyeth, and that therefore the sales contract statute of limitations must apply, citing *Aube v. O'Brien*, 433 A.2d 298 (Vt. 1981). Even were this Court able to find that Kellogg's claims arise out of a sale of goods, and that she was in privity with Wyeth, *Aube's* holding is consistent with the principle that one examines the nature of the harm to determine the applicable statute of limitations.

Aube involved the sale of cows infected with brucellosis, and alleged counts of strict tort liability, negligence, fraud, and breach of express and implied warranties. The plaintiff sought compensatory and punitive damages for the loss of cattle, loss of milk production and general business losses. At issue was whether the three-year statute of limitations for damage to personal property or the four-year statute of limitations for breach of a contract for sale applied. Finding that the dispute concerned a classic commercial transaction for which contractual damages were potentially recoverable, the Vermont Supreme Court concluded that the sales contract statute of limitations applied. *Id.* at 300.

If one looks to the nature of the harm rather than the specific cause of action asserted, Kellogg seeks recovery for bodily injury, allegedly sustained as a result of the actions or failures to act of the drug company defendants. As such, her claims fall squarely within the three-year statute of limitations applicable to personal injury claims. Wyeth is not entitled to summary judgment on Counts 7 and 8 for failure to file suit within the applicable statute of limitations.

IV. Claims Against Wyeth, as the Brand Name Manufacturer

Kellogg has asserted counts against Wyeth as the manufacturer of Reglan®, for negligent misrepresentation, fraud and fraud by concealment, on the theory that Wyeth negligently or fraudulently disseminated inaccurate and misleading information concerning the properties and effects of its drug to physicians, which then led her doctors to overprescribe MCP to her. Wyeth contends that it cannot be held liable for injuries that may have been caused by MCP manufactured by another drug company.

Although Kellogg's claims against the generic manufacturers of MCP are "strict product liability" claims, her claims against Wyeth as the brand name manufacturer sound in negligence and fraud. Wyeth contends that regardless of the label Kellogg attaches to these claims, they are product liability claims, and require that the manufacturer have sold the product that caused the injury. *See, e.g., Farnham v. Bombardier, Inc.*, 640 A.2d 47,

48 (Vt. 1994) ("To establish strict liability in a products liability action, a plaintiff must show that the defendant's product . . . caused injury to the consumer" (citing Restatement (Second) of Torts § 402A (1965))).⁵ Under Vermont law, "[t]o establish strict liability for an inadequate warning, a plaintiff must prove that the inadequate warning made the product unreasonably dangerous and was the proximate cause of the injury," *Webb*, 692 A.2d at 347, "but is relieved of showing that the defendant was negligent." *Id.*⁶

To date, however, Vermont has not eliminated common law actions for negligence or fraud merely because they involve products. "[A]ll common law that is 'not repugnant to the

⁵ As support for its argument, Wyeth emphasizes the *McCulloch* court's comment that "[w]hile strict liability and negligence are analytically distinct claims, they become one where liability rests on a failure to warn." *McCulloch*, 61 F.3d at 1044. Wyeth reads too much into the comment, a summary of strict product liability principles, which notes that a product manufacturer escapes liability for its product absent proof that the manufacturer knew or should have known of the risk about which it failed to warn. See *id.* (quoting W. Page Keeton et al., *Prosser & Keeton on Torts*, § 99, at 697 (5th ed. 1984)). The Prosser & Keeton hornbook of course distinguishes between strict liability and negligence, defining strict liability in part as "liability that is imposed on an actor apart from . . . a breach of a duty to exercise reasonable care." § 75 at 534.

⁶ Concerning the issue under consideration in *Webb*, whether and how to apply principles of comparative liability to strict liability cases, the Vermont Supreme Court did not produce a majority opinion. However, a majority of the Justices agreed that a plaintiff in a strict product liability action need not show that the defendant was negligent. See *Webb*, 692 A.2d at 350 (plurality op.), 356 (Johnson, J., dissenting).

constitution or laws shall be laws' in Vermont." *Langle v. Kurkul*, 510 A.2d 1301, 1303 (Vt. 1986) (quoting Vt. Stat. Ann. tit. 1, § 271). Neither the Vermont courts nor the Vermont legislature have collapsed negligence actions into strict liability actions where products are involved. See *Webb*, 692 A.2d at 350 ("Nothing in our case law suggests that some products liability cases are based on negligence principles and others are not," discussing application of comparative liability principles to product liability actions); cf. *Densberger v. United Techs. Corp.*, 297 F.3d 66, 71 (2d Cir. 2002) (holding that because Connecticut's Product Liability Act "does not expressly prohibit post-sale liability for negligent failure to warn, the negligence-based common law duty survives and is cognizable . . ."); *Carrel v. Allied Prods. Corp.*, 677 N.E.2d 795, 798-99 (Ohio 1997) (concluding that common law negligence actions survived legislature's codification of products liability law).

Under Vermont law,

[t]he elements required for a cause of action in common law negligence are: (1) the defendant must owe a legal duty to conform to a certain standard of conduct so as to protect the plaintiff from an unreasonable risk of harm; (2) the defendant must have committed a breach of this duty by failing to conform to the standard of conduct required; (3) the defendant's conduct must be the proximate cause of the plaintiff's injury; and (4) the plaintiff must have suffered actual loss or damage.

Langle, 510 A.2d at 1304 (emphases omitted). An action for fraud requires "an intentional misrepresentation of existing fact,

affecting the essence of the transaction, so long as the misrepresentation was false when made and known to be false by the maker, was not open to the defrauded party's knowledge, and was relied on by the defrauded party to his damage.'"

Bennington Housing Auth. v. Bush, 2007 VT 60, ¶ 8, 933 A.2d 207, 210-11 (quoting *Union Bank v. Jones*, 411 A.2d 1338, 1342 (1980)). An action for fraud may also be based on "the failure to disclose material facts . . . by one with knowledge and a duty to disclose.'" *Sugarline Assocs. v. Alpen Assocs.*, 586 A.2d 1115, 1119 (Vt. 1990) (quoting *Standard Packaging Corp. v. Julian Goodrich Architects, Inc.*, 392 A.2d 402, 404 (1978)); accord *Ianelli v. U.S. Bank*, 2010 VT 34, ¶ 14 n.*, 996 A.2d 722, 727.

A. Legal Duty

"Whether there is a legal duty is primarily a question of law, dependent upon a variety of relevant factors . . . of which 'foreseeability of the risk is a primary consideration'" *Langle*, 510 A.2d at 1305 (quoting *Coulter v. Superior Court*, 577 P.2d 669, 674 (Cal. 1968)); accord *Green v. Sherburne Corp.*, 403 A.2d 278, 280 (Vt. 1979) ("It has been the law of Vermont for many years that the standard of conduct needed to discharge a duty of care in any given situation was measured in terms of the avoidance of reasonably foreseeable risks to the person to whom such duty is owed."); see also *Smith v. Day*, 538 A.2d 157, 159 (Vt. 1987) (declining to recognize a duty for which there was

"absolutely no reasonably foreseeable notice"); *Peck v. Counseling Serv. of Addison County, Inc.*, 499 A.2d 422, 426 (1985) (recognizing a therapist's duty to take reasonably necessary steps to protect the foreseeable party at risk of violence from a patient). "Ultimately, whether a duty exists is a question of fairness that depends on, among other factors, the relationship of the parties, the nature of the risk, and the public interest at stake." *Hamill v. Pawtucket Mut. Ins. Co.*, 2005 VT 133, ¶ 6, 892 A.2d 226, 228.

The parties agree that a drug manufacturer has a duty to warn physicians about the risks associated with use of the drug in the context of strict products liability. In the context of a negligence action, the duty owed by a drug manufacturer to a physician is to exercise due care in disseminating information about its product in order to avoid reasonably foreseeable risks. Although Wyeth acknowledges that it has a duty to provide an adequate warning about Reglan® to physicians in order that they may appropriately advise their patients, it contends that it has no duty to a doctor who prescribes Reglan® if the pharmacy fills the doctor's prescription with generic and bioequivalent MCP, pursuant to law.

Essentially, it is the scope, not the existence of a duty of care that is at issue under these circumstances. Wyeth is obliged to exercise due care in disseminating information about

Reglan® to all physicians. At issue is whether it is reasonably foreseeable that a doctor, in reliance upon false or misleading information disseminated by a brand name drug manufacturer, will write a prescription that will be filled by the bioequivalent generic form of the drug.

Kellogg has submitted evidence that doctors routinely rely on information provided by the brand name manufacturers of drugs, in particular on the PDR. Nelson Decl. ¶ 5. Typically, the PDR includes label information for brand name drugs, not the generic equivalents, and before 2005 it would have been difficult for a prescribing physician to obtain the product information for a generic version of the drug. *Id.* ¶¶ 6, 8. Usually the prescriber will not know which generic version will be dispensed by the pharmacy. *Id.* ¶ 8. Kellogg's evidence suggests that doctors rely upon the brand name drug manufacturer for the superior information it has as the product originator, not for the quality of its manufacturing process.

A pharmacist is required by law to substitute the lowest priced generic equivalent when filling a prescription for a drug, unless otherwise instructed by the prescriber. See Vt. Stat. Ann. tit. 18, 4605(a). It is routine, therefore, and entirely foreseeable, that a physician will prescribe a drug in reliance upon information disseminated by the brand name manufacturer, and that the patient will receive and ingest a generic equivalent.

See Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 315 (Cal. Ct. App. 2008) (“[T]he conclusion [is] inescapable that Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them.”), *review denied*, 2009 Cal. LEXIS 233 (2009).

The question remains whether it is “fair” to acknowledge this duty. The parties have advanced a variety of public policy reasons to allow or refuse to allow negligent or fraudulent misrepresentation claims against a brand name drug manufacturer. Their briefs contain broad, competing, and fairly speculative contentions that lack factual support in the record to date. For example, Wyeth argues that such an acknowledgment “would effectively create an insurance system in favor of generic drug manufacturers, which do not need one[,] . . . that name brand manufacturers would remain the guarantors of [the] product lines long after their exclusive rights expire.” Def. Wyeth’s Mot. for Summ. J. 28 (citing *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (finding it “unfair” to allow brand name manufacturer liability when a generic manufacturer copies its labels and takes advantage of its advertising)). The *Conte* court found this argument “problematic.” *Conte*, 85 Cal. Rptr. 3d at 317 (“[W]hat is unfair about requiring a defendant to shoulder its share of responsibility for injuries caused, at least in

part, by its negligent or intentional dissemination of inaccurate information?").

In her negligent misrepresentation claim, Kellogg seeks to hold Wyeth liable for its failure to use due care in disseminating information about MCP; she does not seek to hold Wyeth strictly liable for a defective or unreasonably dangerous product. See *id.* at 309-10. If she can establish that Wyeth's conduct was negligent, and was the proximate cause of her injury, then she may recover; this is far from a grant of immunity to the generic drug manufacturers, who continue to face strict product liability claims.

To recognize that a brand name drug manufacturer owes a duty to use reasonable care to avoid causing injury to consumers of the generic bioequivalents of its drugs does not "recognize a new cause of action or enlarge an existing one," *Langle*, 510 A.2d at 1306, an activity inappropriate for a federal district court sitting in diversity to undertake. The broader public policy issues are worthy of debate, but unnecessary for the determination of whether Kellogg's claims against Wyeth as the brand name manufacturer can proceed. This Court has simply applied the basic precepts of Vermont's negligence law to ascertain whether a legally cognizable duty exists, and has

concluded that it does.⁷

Wyeth asserts that Vermont should follow a "national rule" that the manufacturer of a brand name drug cannot be held liable for injuries caused by a generic equivalent that is manufactured by another company. According to Wyeth, numerous courts in at least twenty states have held that a brand name manufacturer cannot be held liable on a duty to warn theory if the plaintiff took the generic form of the drug, regardless of whether the claim sounds in strict product liability, negligence, misrepresentation or fraud.

The leading case cited for this "rule" is *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994). The infant Foster twins, suffering from colic, were prescribed Phenergan syrup, manufactured by American Home Products Corporation/Wyeth-Ayerst ("Wyeth"). The pharmacy substituted the generic equivalent of the drug. One of the twins died of Sudden Infant Death Syndrome, attributable to use of the drug. *Id.* at 167.

The Fosters sued Wyeth and the generic manufacturer. Their complaint against Wyeth included counts for negligence, strict

⁷ Because it is unnecessary for the disposition of the motions for summary judgment, the Court declines to resolve the parties' debate whether Sections 310 and 311 of the Restatement (Second) of Torts, identifying the torts of conscious and of negligent misrepresentation involving risk of physical harm, are embodied in the common law as it has evolved in Vermont. The Vermont Supreme Court has neither adopted nor rejected these sections of the Restatement.

liability and breach of warranty; the district court found that the Fosters had made out a claim for negligent misrepresentation, distinct from their product liability claim, that did not depend upon Wyeth's having manufactured the drug. It dismissed this claim, however, on the ground that the Fosters could not show that their pediatrician reasonably relied on any representations made by Wyeth. Both parties appealed. *Id.* at 166-67.

The United States Court of Appeals for the Fourth Circuit, interpreting Maryland law, concluded that the Fosters' negligent misrepresentation claim was in actuality a products liability claim that required that the defendant have manufactured the product at issue. *Id.* at 168. It affirmed dismissal of the negligent misrepresentation claim, "on the ground that Maryland law does not recognize a cause of action for negligent misrepresentation against one manufacturer for injuries caused by another manufacturer's product." *Id.* at 172.

In the sixteen years since *Foster* was decided, federal district courts sitting in fifteen states, several state trial courts and one intermediate court of appeal, have also dismissed claims against brand name manufacturers by users of the generic form of the drug.⁸ Some of these decisions were based on state

⁸ One state court, however, has rejected as an inaccurate interpretation of state law a federal district court's opinion that a brand name prescription drug manufacturer owes no duty of care to a plaintiff allegedly injured by a generic equivalent drug. In *Clark v. Pfizer, Inc.*, a Pennsylvania trial court held

statutes that define the scope of permissible actions against manufacturers. *See, e.g., Washington v. Wyeth, Inc.*, No. 3:09-CV-01343, 2010 WL 450351 (W.D. La. Feb. 8, 2010); *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056, 1059-60 (W.D. Ark. 2009); *Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2008 WL 2677051, at *2-3 (W.D. Ky. June 30, 2008); *Westerlund v. Wyeth, Inc.*, No. MID-2174-05, slip op. at 3 (N.J. Super. Ct. Law Div. Oct. 20, 2008). Vermont has not enacted such a statute.

Recently the United States Court of Appeals for the Eighth Circuit, in a case involving MCP, concluded that "holding name brand manufacturers liable for harm caused by generic manufacturers 'stretch[es] the concept of foreseeability too far.'" *Mensing v. Wyeth*, 588 F.3d 603, 613 (8th Cir. 2009) (quoting *Foster*, 29 F.3d at 171), *petition for cert. filed*, 78 U.S.L.W. 3522 (U.S. Feb. 19, 2010) (No. 09-993). It held "that under Minnesota law [the plaintiff] has not shown that the name brand manufacturers owed her a duty of care necessary to trigger liability." *Id.* at 614. The *Mensing* court concluded that a duty of care does not extend to all potential Reglan® consumers, and declined to predict that the Minnesota Supreme Court would

that a brand name manufacturer may be liable for negligent or intentional misrepresentation that deluded the medical community into believing a drug was effective. *Clark v. Pfizer Inc.*, No. 1819, 2008 Phila. Ct. Com. Pl. LEXIS 242, at *27-29 (C.P. Phila. Mar. 12, 2008) (examining Pennsylvania law, rejecting *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009)).

recognize a claim for negligent misrepresentation under these circumstances. *Id.* at 613-14 (citing *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350 (Minn. App. 2001)).⁹

By contrast, the California Court of Appeal has held that a negligent misrepresentation claim is viable against a brand name manufacturer. In *Conte v. Wyeth, Inc.*, a user of generic MCP who developed tardive dyskinesia brought suit against Wyeth for negligent misrepresentation, fraud and fraud by concealment. 85 Cal. Rptr. 3d at 305. The trial court granted Wyeth's motion for summary judgment on the grounds that neither Conte nor her doctor relied on drug information provided by Wyeth, and that Wyeth owed no duty of care to the users of generic MCP. *Id.* at 306.

The *Conte* court dismissed the notion that Conte's claims were strict product liability claims disguised as misrepresentation and fraud claims:

Negligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury. . . . Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the

⁹ In *Flynn*, the consumer of a generic weight-loss medicine brought suit against the brand name manufacturer, alleging that misrepresentations the manufacturer made to the FDA caused her to ingest a generic version of the drug, which injured her. 627 N.W.2d at 344. The Minnesota Court of Appeals refused to recognize this "fraud-on-the-FDA" tort, concluding that whatever obligation the manufacturer had to communicate with the FDA did not extend to third parties. *Id.* at 350.

acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in strict liability as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.

Id. at 310. It examined the question whether a brand name manufacturer owes a duty of care to patients who take a generic form of the drug, and concluded "that Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them." *Id.* at 315. It held "that Wyeth's duty of care in disseminating product information extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in reliance on Wyeth's product information for Reglan." *Id.*

Ultimately, although the decisions from other jurisdictions may offer insight, this Court seeks to follow the common law as it has developed in Vermont. There is no reason, under Vermont law, to limit Wyeth's duty of care to physicians by the pharmacist's choice of a generic bioequivalent drug to fill the physician's prescription. As discussed above, under Vermont's negligence law it is reasonably foreseeable that a physician will

rely upon a brand name manufacturer's representations--or the absence of representations--about the risk of side effects of its drug, when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug. Vermont allows a negligence action against one who owes a duty of care and fails to conform to the standard of conduct required.

B. Reliance

Wyeth also argues that Kellogg's misrepresentation and fraud claims fail because she cannot prove that her doctors relied on the false or misleading information it allegedly provided.¹⁰ Without proof of reliance she cannot prove that the false or misleading information caused her injury.

Both doctors stated that when they prescribed MCP they believed that the risk of developing tardive dyskinesia was comparatively rare. Both had used the PDR, which contained

¹⁰ The parties agree that Kellogg will have to prove that her doctors relied on Wyeth to provide accurate and not misleading information. See, e.g., *Repucci v. Lake Champagne Campground, Inc.*, 251 F. Supp. 2d 1235, 1238 (D. Vt. 2002) (stating that justifiable reliance is required in order to recover for negligent misrepresentation, citing *Howard v. Usiak*, 775 A.2d 909, 912-13 (Vt. 2001) and Restatement (Second) of Torts § 552(1) (1977)); *Silva v. Stevens*, 589 A.2d 852, 857 (Vt. 1991) (stating that an action for fraud and deceit requires reliance upon an intentional misrepresentation, quoting *Union Bank v. Jones*, 411 A.2d 1338, 1342 (Vt. 1980)); *Fuller v. Banknorth Mortg. Co.*, 788 A.2d 14, 16 (Vt. 2001) (stating that elements of fraudulent concealment include "detrimental reliance by the defrauded party").

Wyeth's Reglan® label information, although neither had a specific recollection of consulting the PDR before prescribing the drug for Kellogg. Kellogg has provided evidence that the "comparatively rare" ratio of 1 in 500 for extrapyramidal symptoms was inaccurate and misleading. See Nelson Decl. ¶27. She contends that this misinformation is traceable to Wyeth or its predecessor, AHR. *Id.* ¶ 34.¹¹

Kellogg has also alleged that Wyeth concealed information from physicians that would have affected their decision to prescribe Reglan®, see, e.g., *id.* ¶ 10; in particular that AHR had disseminated unscientific and false information that long-term MCP therapy was reasonably safe, see *id.* ¶ 17; that long-term treatment with MCP can be expected to lead to tardive dyskinesia and other extrapyramidal symptoms with about the same frequency as other neuroleptic agents, see *id.* ¶ 27; and that long-term treatment with MCP is unlikely to be reasonably safe. See *id.* ¶ 20. She has provided evidence that AHR downplayed the harmful effects of long-term treatment with the drug, in an effort to increase sales and encourage long-term off-label use of

¹¹ Wyeth asserts that the admissibility of Kellogg's expert's opinion that the misinformation is traceable to Wyeth is "extremely doubtful . . . as unscientific speculation," that would not meet the standards of Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Wyeth may of course file a *Daubert* motion in advance of trial, but it would be premature to exclude the opinion in the absence of full briefing on the issue.

the drug. See *id.* ¶ 17.

More important, Kellogg's doctors have testified that they rely on a prescription drug's manufacturers to inform them of the drug's risks and to provide updated information should it become apparent that the drug's risks are inaccurately set out in the PDR. See *Wyeth v. Levine*, 129 S. Ct. at 1196 (commenting that manufacturers remain responsible for updating their labels to strengthen warnings if additional risk information becomes available). Dr. Armstrong stated that had he known about the additional information that now appears in the "black box warning" for MCP, he would have stopped prescribing it for Kellogg.

It remains to be seen whether Kellogg can establish at trial that her doctors relied on inaccurate and misleading information--or the absence of accurate information--from Wyeth concerning the risks and effects of long-term use of MCP. For purposes of withstanding Wyeth's motion for summary judgment, Kellogg has pointed to triable issues of fact on the issue of reliance. It is for a jury to decide whether the doctors relied on false or misleading information traceable to Wyeth.

Conclusion

For the reasons stated above, Wyeth's motion for summary judgment is **denied**. Actavis's motion for summary judgment is **denied**.

Dated at Burlington, in the District of Vermont, this 20th
day of October, 2010.

/s/ William K. Sessions III
William K. Sessions III
Chief Judge
U.S. District Court